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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,735	09/24/1999	GERALD B. PIER	B0801/7155	9816

7590 03/27/2002
HELEN C LOCKHART
WOLF GREENFIELD & SACKS P C
600 ATLANTIC AVENUE
BOSTON, MA 02210

EXAMINER	
SIEW, JEFFREY	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,735

Applicant(s)

PIER, GERALD B.

Examiner

Jeffrey Siew

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1656

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1637, and is assigned to Patent Examiner Jeffrey Siew.

Election/Restrictions

2. Applicant's election with traverse of Group II in Paper No. 12 is acknowledged. The response has not submitted any arguments at the time of this writing.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-13 & 44-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.12.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "therapeutically effective amount" renders claims 14-22 & 24 indefinite because it is unclear as to what disease the preparation is to be therapeutic for. Consequently the effective amount is indeterminate.

B) Claims 14-43 are confusing because it is unclear whether the claims scope may also be inclusive of fatty acid portions of LPS structure.

C) The term "biocompatible" is indefinite. It is unclear the meaning of the term in view of the claims. It is unclear whether the term refers to a pharmaceutical effect, beneficial or lack of harmful effect in an organism.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 26-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Masoud et al (J. of Bacteriology Dec. 1995 pp. 6718-6726).

Masoud et al teach the isolation of lipopolysaccharide core of P. aeruginosa (see whole doc.). They teach that the core contains an alanine (see Table 2 & Figure 8 & 9).

The term "bioactive agent" and "covalent conjugate" are interpreted broadly to include the lipo portions of the lipopolysaccharide.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-23 & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masoud et al (J. of Bacteriology Dec. 1995 pp. 6718-6726) in view of Pennington et al (J. of Inf. Diseases vol. 144 (6) pp. 599-603).

Pennington et al teach a lipopolysaccharide vaccine preparation from P. aeruginosa (see whole doc.).

Pennington et al do not teach the LPS of the claimed structure.

Masoud et al teach the isolation of lipopolysaccharide core of P. aeruginosa (see whole doc.). They teach that the core contains an alanine (see Table 2 & Figure 8 & 9).

Art Unit: 1656

One of ordinary skill in the art would have been motivated to apply Masoud et al's isolated *P. aeruginosa* LPS to Pennington et al's vaccine in order to create species specific vaccine for *P. Aeruginosa* vaccine. Masoud et al teach that *P. aeruginosa* often cause fatal infections and the LPS is surface antigen in the outer membrane. As Pennington et al teach that the *P. Aeruginosa* vaccine induced greater serum titers for superior detection, it would have been prima facie obvious to apply Masoud et al's teaching of successful isolation of LPS to Masoud et al's teachings to create an effective vaccine preparation.

SUMMARY

7. No claims allowed. However claim 24 is free of the prior art. There is no art that teach or suggest the claimed lipopolysaccharide core of *P. aeruginosa* in aerosol form.

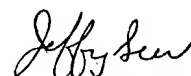
CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Art Unit: 1656

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.



Jeffrey Siew
Primary Examiner
March 23, 2002